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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,081	05/02/2001	Marco Busch	Mo-6314/LeA 34,326	7196

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	15

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/847,081	BUSCH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 October 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 and 25-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-21 and 25-38 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Application Status***

Claims 1-21 and 25-38 are pending in the application.

Applicants' amendment to claims 1-21 and 25-27, cancellation of claims 22-24, and addition of claims 28-38 in Paper No. 11, filed 05/02/01, is acknowledged.

Applicants' election of Group VIII, claims 20, 21, 33, and 34 in Paper No. 14, filed 10/07/02, is acknowledged. No traversal was set forth in this response.

The previous Office action (Paper No. 12) was a restriction requirement of pending Claims 1-21 and 25-38. Applicants responded to said Office action by electing Group VIII as indicated in Paper No. 14. No traversal was set forth in this response. This supplemental restriction requirement is at the discretion of the Examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary as a plurality of patentably distinct inventions are encompassed by the claims of the elected Group. In a telephone conversation with Mr. Raymond J. Harmuth on 11/18/02, the examiner requested a telephonic election of a polypeptide selected from SEQ ID NO: 2, 4, or 6 for examination of the claims of Group VIII. Instead of electing telephonically, Mr. Harmuth requested a paper copy of a supplemental restriction requirement for election of a polypeptide of SEQ ID NO: 2, 4, or 6 for examination of the claims of Group VIII. As requested, the instant Office action is a supplemental restriction requirement.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 19 and 38, drawn to the nucleic acid of SEQ ID NO:1, a nucleic acid encoding SEQ ID NO:2, and variants thereof, and a method of generating a polypeptide, classified in class 435, subclass 193.
  - II. Claims 19 and 38, drawn to the nucleic acid of SEQ ID NO:3, a nucleic acid encoding SEQ ID NO:4, and variants thereof, and a method for generating a polypeptide, classified in class 435, subclass 193.

- III. Claims 1-6, 8-13, 19, 29-32, 36, and 38, drawn to the nucleic acid of SEQ ID NO:5, a nucleic acid encoding SEQ ID NO:6, variants and fragments thereof, a DNA construct, a vector, a method of transformation, a method for generating a polypeptide, transformed host cells, and transformed plants classified in class 435, subclass 410.
- IV. Claims 7 and 28, drawn to a nucleic acid regulatory region which controls transcription of a nucleic acid encoding SEQ ID NO:6, classified in class 536, subclass 24.1.
- V. Claim 14, drawn to the phytoene synthase 1 polypeptide of SEQ ID NO:2 encoded by SEQ ID NO:1, classified in class 435, subclass 193.
- VI. Claim 14, drawn to the phytoene synthase 2 polypeptide of SEQ ID NO:4 encoded by SEQ ID NO:3, classified in class 435, subclass 193.
- VII. Claim 15, drawn to the zeta-carotene desaturase polypeptide of SEQ ID NO:6 encoded by SEQ ID NO:1, classified in class 435, subclass 189.
- VIII. Claim 16, drawn to an antibody that binds SEQ ID NO:2, classified in class 530, subclass 387.9.
- IX. Claim 16, drawn to an antibody that binds SEQ ID NO:4, classified in class 530, subclass 387.9.
- X. Claim 17, drawn to an antibody that binds SEQ ID NO:6, classified in class 530, subclass 387.9.
- XI. Claim 18, drawn to a process for generating a nucleic acid encoding SEQ ID NO:6, classified in class 435, subclass 91.5.
- XII. Claims 20 and 33, drawn to a method of finding a chemical compound that binds to the polypeptide of SEQ ID NO:2, classified in class 435, subclass 15.
- XIII. Claims 20 and 33, drawn to a method of finding a chemical compound that binds to the polypeptide of SEQ ID NO:4, classified in class 435, subclass 15.
- XIV. Claims 20 and 33, drawn to a method of finding a chemical compound that binds to the polypeptide of SEQ ID NO:6, classified in class 435, subclass 25.

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- XV. Claims 21 and 34, drawn to a method of finding a compound that modifies the expression of the polypeptide of SEQ ID NO:2, classified in class 435, subclass 6.
- XVI. Claims 21 and 34, drawn to a method of finding a compound that modifies the expression of the polypeptide of SEQ ID NO:4, classified in class 435, subclass 6.
- XVII. Claim 34, drawn to a method of finding a compound that modifies the expression of the polypeptide of SEQ ID NO:6, classified in class 435, subclass 6.
- XVIII. Claim 25, drawn to a plant with increased expression or activity of an antibody that binds the polypeptide of SEQ ID NO:2, classified in class 800, subclass 295.
- XIX. Claim 25, drawn to a plant with increased expression or activity of an antibody that binds the polypeptide of SEQ ID NO:4, classified in class 800, subclass 295.
- XX. Claim 35, drawn to a plant with increased expression or activity of an antibody that binds the polypeptide of SEQ ID NO:6, classified in class 800, subclass 295.
- XXI. Claim 26, drawn to a plant with increased expression or activity of the polypeptide of SEQ ID NO:2, classified in class 800, subclass 295.
- XXII. Claim 26, drawn to a plant with increased expression or activity of the polypeptide of SEQ ID NO:4, classified in class 800, subclass 295.
- XXIII. Claim 27, drawn to a method of generating plants with increased expression or activity of the polypeptide of SEQ ID NO:6 by endogenous mutagenesis of a nucleic acid encoding SEQ ID NO:6, classified in class 800, subclass 276.
- XXIV. Claim 37, drawn to a method of generating plants with increased expression or activity of the polypeptide of SEQ ID NO:6 by endogenous mutagenesis of a regulatory region that controls transcription of a nucleic acid encoding SEQ ID NO:6, classified in class 800, subclass 276.

2. The inventions are distinct, each from the other because:

3. The polynucleotides of Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of the polynucleotides of Groups I-IV are structurally distinct and, where structural identity is required, such as for hybridization or the expression of polypeptides, the different sequences have different effects.

4. The polypeptides of Groups V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of the polypeptides of Groups V-VII are structurally distinct and, where structural identity is required, such as for production of antibodies, the different polypeptide sequences have different effects.

5. The antibodies of Groups VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of the antibodies of Groups VIII-X are structurally and functionally distinct and, where structural identity is required, such as for binding to polypeptides, the different antibodies have different effects.

6. The plants of Groups XVIII-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of the plants of Groups XVIII-XXII comprise antibodies or polypeptides that are structurally distinct and, where structural identity is required, such as for production of antibodies using polypeptides or binding of polypeptides using antibodies, the different sequences have different effects.

7. The polynucleotide of Groups I-IV, the polypeptide of Groups V-VII, the antibody of Groups VIII-X, and the plant of Groups XVIII-XXII each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide of Groups I-IV has other utility besides encoding polypeptides such as a hybridization probe, the polypeptides of Groups V-VII can be made by another method such as purification from the natural source or *in vitro* synthesis, the antibody can be used to

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purify the polypeptide of Groups VIII-X, and the plant of Groups XVIII-XXII can be used for the production of a polypeptide or antibody.

8. The processes or methods of Groups XI-XVII, XXIII, and XXIV are independent as they comprise different steps, utilize different products and/or yield different results.

9. The polynucleotide of Groups I and II is unrelated to the method(s) of Groups XI-XIV, XVII, XXIII, and XXIV as it is neither used nor made by the method(s) of Groups XI-XIV, XVII, XXIII, and XXIV.

10. The polynucleotide of Groups I and II and the methods of Groups XV and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Groups I and II can be used for polypeptide expression.

11. The polynucleotide of Group III is unrelated to the method(s) of Groups XII-XVI and XXIV as it is neither used nor made by the method(s) of Groups XII-XVI and XXIV.

12. The polynucleotide of Group III and the method of Group XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case chemical synthesis can be used to produce nucleic acids that are structurally distinct from the polynucleotide of Group III.

13. The polynucleotide of Group III and the methods of Groups XVII and XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group III can be used as a hybridization probe.

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14. The polynucleotide of Group IV is unrelated to the method(s) of Groups XI-XVII, XXIII, and XXIV as it is neither used nor made by the method(s) of Groups XI-XVII, XXIII, and XXIV.

15. The polynucleotide of Group IV and the method of Group XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group IV can be used for polypeptide expression.

16. The polypeptide of Group V is unrelated to the method(s) of Groups XI, XIII-XVII, XXIII, and XXIV as it is neither used nor made by the method(s) of Groups XI, XIII-XVII, XXIII, and XXIV.

17. The polypeptide of Group V and the method of Group XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used as an antigen in the production of antibodies.

18. The polypeptide of Group VI is unrelated to the method(s) of Groups XI-XII, XIV-XVII, XXIII, and XXIV as it is neither used nor made by the method(s) of Groups XI-XII, XIV-XVII, XXIII, and XXIV.

19. The polypeptide of Group VI and the method of Group XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used as an antigen in the production of antibodies.

20. The polypeptide of Group VII is unrelated to the method(s) of Groups XI-XIII, XV-XVII, XXIII, and XXIV as it is neither used nor made by the method(s) of Groups XI-XIII, XV-XVII, XXIII, and XXIV.

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21. The polypeptide of Group VII and the method of Group XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used as an antigen in the production of antibodies.

22. The antibody of Groups VIII-X is unrelated to the method(s) of Groups XI-XVII, XXIII, and XXIV as it is neither used nor made by the method(s) of Groups XI-XVII, XXIII, and XXIV.

23. The plant of Groups XVIII-XXII is unrelated to the method(s) of Groups XI-XVII, XXIII, and XXIV as it is neither used nor made by the method(s) of Groups XI-XVII, XXIII, and XXIV.

24. MPEP 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02". Because the inventions of Groups I-XXIV are distinct for the reasons given above, have separate classification, and/or each of the inventions requires a separate patent and non-patent literature and/or sequence search, restriction for examination purposes is proper.

25. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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27. Claims 14, 16, 25-27, 37, and 38 will be examined to the extent the claims read on the elected subject matter.

28. It is noted that claim 19 has been included in Groups I-III. While the claim is drawn to a method for generating a polypeptide of claim 14 (the polypeptide of SEQ ID NO:2 or 4), the claim recites using a host cell expressing the polypeptide of SEQ ID NO:6. In order to expedite prosecution, the claim has been included in all of Groups I-III. It is suggested that applicants amend the claim to clarify its meaning.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652



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